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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,871	04/28/2000	John F. Norris	P-8873	3151

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EXAMINER

DROESCH, KRISTEN L

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/558,871

Applicant(s)

NORRIS ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10, 13-15, 17-22, 25, 30-43 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-8, 10, 12-15, 17-21, 25, 30 and 45-58 is/are allowed.
- 6) ☒ Claim(s) 22, 31-34, 37, 43 is/are rejected.
- 7) ☒ Claim(s) 35, 36 and 38-42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Objections*

1. Claim 22 is objected to because of the following informalities: “(iii) differences in T-wave characteristics over a series of two or more heartbeats” merely restates what has already been set forth in the claim language. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 22 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al. (6,058,328).

With respect to claim 22, Levine et al. shows a device and method comprising sensing electrical cardiac activity using an implanted sensor and evaluating cardiac risk based on a comparison of the indication of T-wave alternans to a predetermined criterion based on analysis of differences in T-wave characteristics (time of occurrence following Q wave) over a series of two or more heartbeats (Col. 13, line 34-Col. 14, line 53, Col. 28, line 38-Col. 29, line 16, Col. 33, lines 42-61).

Regarding claim 31, Levine et al. shows an implantable medical device comprising a pacing generator, one or more leads coupled to the pacing generator, an electrical cardiac activity sensor, and a T-wave analyzer responsive to the sensor that controls the pacing generator to

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generate increases rate electrical pacing stimuli, and analyzes cardiac risk based on a comparison of the indication of T-wave alternans to a predetermined criterion (Col. 15, line 14-30, Col. 13, line 34-Col. 14, line 53, Col. 28, line 38-Col. 29, line 16, Col. 33, lines 42-61).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claim 32, Levine et al. shows a memory (Col. 28, lines 55-59).

Regarding claim 33, Levine et al. shows providing an alert by initiating preemptive tachycardia pacing therapy.

Regarding claim 34, Levine et al. shows the T-wave analyzer analyzes differences in the QT interval over a series of two or more heartbeats to evaluate cardiac risk (Col. 33, lines 42-61).

With respect to claim 37, Levine et al. shows the T-wave analyzer analyzes differences in the T-wave characteristics (time of occurrence following Q wave) over a series of two or more heartbeats to evaluate cardiac risk (Col. 33, lines 42-61).

With respect to claim 43, Levine et al. shows a pacing generator that applies pacing stimuli and a processor or controller that controls the pacing generator based on the indication of T-wave alternans (Col. 13, line 34-Col. 14, line 53, Col. 15, line 14-30, Col. 28, line 38-Col. 29, line 16, Col. 33, lines 42-61).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

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***Allowable Subject Matter***

4. Claims 2-8, 10, 12, 13-15, 17-21, 25, 30, and 45-58 are allowed.
5. Claims 35-36, and 38-42 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

6. Applicant's arguments filed 10/7/03 have been fully considered but they are not persuasive.
7. Regarding claim 31, the addition of "whereby the desired physiological conditions for a T-wave alternans analysis can be invoked" is deemed to be language of intended use and therefore has not been considered to impose any structural limitations on the device as claimed. Levine et al. applies increased rate pacing as preemptive tachyarrhythmia therapy to shorten the QT interval (Col. 33, lines 51-57). But, it is possible that the desired physiological conditions for T-wave alternans analysis can be invoked by the increased pacing rate stimuli applied as preemptive tachyarrhythmia therapy since it would be dependent on the individual patient's physiological response.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

*Kristen Drosch*

kld

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